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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

February 22, 2002

Ref: 2002-DAL-WL-11

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Mark A. Brumback, President
Hearing Aid Express
11888 Marsh Lane, Suite # 111
Dallas, Texas 75234

Dear Mr. Brumback:

On December 18 through 21, 2001, our FDA investigator conducted an establishment inspection of your device manufacturing facility located in Dallas, Texas. Our investigator determined that your firm manufactures several models of Air Conduction Hearing Aid devices, such as the Full Shell Air Conduction Hearing Aid, Canal Air Conduction Hearing Aid, Push Pull Air Conduction Hearing Aid, and Ultra Mini Air Conduction Hearing Aid. These products are medical devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Your devices are adulterated within the meaning of Section 501(h) of the Act in that the methods used in, or the facilities or controls used for their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulations, as specified in Title 21, Code of Federal Regulation (CFR), Part 820. Significant GMP deviations include, but are not limited to, the following:

1. Failure to conduct management reviews at defined intervals [21 CFR 820.20(c)] [FDA-483 Item 2].

2. Failure to conduct internal quality audits at defined intervals according to your firm's written procedures [21 CFR 820.22] [FDA-483 Item 3].

3. Failure to document employee training and failure to establish procedures for identifying employee training needs [21 CFR 820.25(b)] [FDA-483 Items 4 and 5].

4. Failure to analyze processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify and document existing and potential causes of non-conforming product, or other quality problems [21 CFR 820.100(a)(1)]. For example, from January, 2001 through June, 2001, your firm received 146 defective hearing aids for repair but did not trend the repair data for unfavorable trends and for determining if a quality or product problem existed [FDA-483 Item 6].

5. Failure to establish complete corrective and prevent action procedures that address all requirements in 21 CFR 820.100(a)(1) through (b) [FDA-483 Item 7].

6. Failure to establish procedures for the identification, documentation, evaluation, segregation, and disposition of nonconforming product [21 CFR 820.90]. For example:

   (a) Procedures for rework of nonconforming product have not been established [FDA-483 Item 12]; and

   (b) Rework activities performed have not been documented in the device history records [FDA-483 Item 13]; and

   (c) There is no documentation of the disposition of nonconforming product. For example, hearing aid shells that failed to meet fabrication specifications were scrapped, and new shells were fabricated, and this was not documented [FDA-483 Item 14].

7. Failure to investigate and document defective hearing aids returned to your firm for repair for determining possible root causes and product quality trends [21 CFR 820.198 (c)] [FDA-483 Item 8].

8. Failure to conduct and document testing verification or validation of manufacturing process changes [21 CFR 820.75(c)]. For example, your firm could not provide documentation of any tests and/or evaluation conducted to ensure that the change in the fabrication process from a [redacted]-curing process to a [redacted] curing process does not affect the quality of the hearing aid shell [FDA-483 Item 11].

9. Failure to evaluate suppliers on the basis of their ability to meet specified requirements, including quality requirements [21 CFR 820.50(a)]. For example, your firm has evaluated and approved current suppliers based on their past performance but has not documented such evaluations [FDA-483 Item 16].

Your firm verbally promised our investigator that it would correct all observations with time frames ranging from 30 days to 90 days, but has not submitted a written response confirming your promise and outlining specific steps your firm has taken or will take to correct the above GMP deficiencies.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and the regulations. The specific violations noted in this letter and in the FDA-483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems.

You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Until these violations are corrected, and FDA has documentation to establish that such corrections have been made, federal agencies will be advised of the issuance of this Warning Letter so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please provide this office in writing within 15 working days of receipt of this letter a report of the specific steps you have taken, or will take to identify and correct any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state

the reason for the delay and the time frame within which the corrections will be completed. Your reply should be directed to Thao Ta, Compliance Officer, at the above letterhead address.

Sincerely,

Michael A. Chappell
Dallas District Director

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